

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS PO Box 1450 Alexasofan, Virginia 22313-1450 www.repto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------------|----------------------|----------------------|------------------|
| 10/588,757 | 06/25/2007 | Roger John Gillespie | 010180.00052 | 2944 |
| 22907 7590 03/12/2009 BANNER & WITCOFF, LTD. | | | EXAMINER | |
| 1100 13th STREET, N.W. | | | STONE, CHRISTOPHER R | |
| SUITE 1200 WASHINGTON, DC 20005-4051 | | | ART UNIT | PAPER NUMBER |
| *************************************** | 71, DC 20000 1001 | | 1614 | |
| | | | | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 03/12/2009 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Application No. Applicant(s) 10/588,757 GILLESPIE ET AL. Office Action Summary Examiner Art Unit CHRISTOPHER R. STONE 1614 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 17 November 2008. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 19.20.23 and 42 is/are pending in the application. 4a) Of the above claim(s) 20 is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) 19 and 23 is/are rejected. 7) Claim(s) 42 is/are objected to 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. Attachment(s)

1) Notice of References Cited (PTO-892)

Information Disclosure Statement(s) (PTO/S5/08)
Paper No(s)/Mail Date _______.

Notice of Draftsperson's Patent Drawing Review (PTO-948)

Interview Summary (PTO-413)
Paper No(s)/Mail Date.

6) Other:

Notice of Informal Patent Application

Art Unit: 1614

DETAILED ACTION

Applicants' arguments, filed November 17, 2008, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Status of Claims

Claims 19, 20, 23 and 42 are currently pending. Claim 20 is withdrawn from consideration as being drawn to a nonelected species. Claims 19, 23 and 42 are currently under examination. In view of the amendment to claim 19, the elected species is now allowable. As such, the examination has been extended to include the compound specie, 2-amino-6-[5-(2-fluoro-4-methylbenzoyl)-2-hydroxyphenyl]-N-[2-(1-pyrrolidinyl)-4-pyrimidinecarboxamide (structure below).

Application/Control Number: 10/588,757 Page 3

Art Unit: 1614

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19 and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Lee et al (WO 2004/080979 A1, listed on IDS filed August 8, 2006).

Lee et al teaches the compound 2-amino-6-[5-(2-fluoro-4-methylbenzoyl)-2-hydroxyphenyl]-N-[2-(1-pyrrolidinyl)ethyl]-4-pyrimidinecarboxamide and pharmaceutical compositions comprising said compound and a pharmaceutically acceptable carrier or excipient (p. 15, compound 6 and p. 26, lines 16-18). It is noted that the negative limitation (c) in the last 3 lines of claim 19 specifies that R₂ is not a phenyl substituted by one or more of the substituents listed in the alternative. The R₂ group of 2-amino-6-[5-(2-fluoro-4-methylbenzoyl)-2-hydroxyphenyl]-N-[2-(1-pyrrolidinyl)ethyl]-4-pyrimidinecarboxamide is not a phenyl substituted by nitro, NH₂, etc.

Claim Objections

Claim 42 is objected to as being dependent upon a rejected base claim, but may be allowable, based on the current search of two species, if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Application/Control Number: 10/588,757

Art Unit: 1614

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER R. STONE whose telephone number is (571)270-3494. The examiner can normally be reached on Monday-Thursday, 7:30am-4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 10/588,757 Page 5

Art Unit: 1614

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

10March2009 CRS

/Patricia A. Duffy/ Primary Examiner, Art Unit 1645